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PPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,448	11/27/2000	Susan J. Clark	Q-61152	5339
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Sughrue Mion Zinn			EXAMINER	
Macpeak & Seas 2100 Pennsylvania Avenue NW			GOLDBERG, JEANINE ANNE	
Washington, DC 20037-3213			ART UNIT	PAPER NUMBER
			1634	. (1)
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Please find below and/or attached an Office communication concerning this application or proceeding.

Application No. Obffice Action Summary Jeanine A Goldberg Jeanine A Goldberg Jeanine A Goldberg Art Unit Jeanine A Goldberg Jeanine A Goldb								
Examiner Jeanine Jean J	•	App	olication No.	Applicant(s)				
Jeanino A Goldberg 1655		09/	673,448	CLARK ET AL.				
The MALING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ± MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Educations to the many is evaluated and the provided and of 12 CPR 139(a), in no event, however, many a reply be timely filed Education to the many to evaluate used the provided and of 12 CPR 139(a), in no event, however, many a reply be timely filed Education to the many to evaluate and the provided and the provided and the provided of the communication of the provided by the provided by the translation period will be statutory information of the reply and the grade the realization of the communication. If the period for reply appendix above, the maximum statutory period will be substationy information of the provided by the the maling date of this communication, even if timely filed, may reduce any communication that application is provided by the CRIS that the communication (s) filed on 14 September 2001. 2a)	Office Action Sum	mary Exa	miner	Art Unit				
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Any reply received by the Office later the milling date of this communication, even if timely filled, may reduce any earned patent term equitarent. See 3 CFR 1.79(b). **Status** 1)	 If NO period for reply is specified above, the 	e maximum statutory period will app	y and will expire SIX (6) M0	NTHS from the mailing date of this communication.				
1) Responsive to communication(s) filed on 14 September 2001. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-50 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are subjected to. 8) Claim(s) 1-50 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some 10 None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 120 and/or 121.	 Any reply received by the Office later than t 	hree months after the mailing date o	the application to become f this communication, even	ABANDONED (35 U.S.C. § 133). if timely filed, may reduce any				
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3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) Other:	2) Notice of Draftsperson's Patent Drawin	ng Review (PTO-948)	5) Notice					

Application/Control Number: 09/673,448

Art Unit: 1655

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-48, drawn to a diagnostic assay for disease characterized by abnormal methylation of cytosine at a site within the glutathione-S-transferase (GST) Pigene.

Group II, claim(s) 49-50, drawn to nucleic acid probes and primers for the GST Pi gene.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The special technical feature of the method of Claim 1 appears to be drawn to the GST Pi gene. The GST Pi gene is not a contribution over the prior art. The specification indicates that the GST-Pi gene sequence is Genbank Accession No. M24485 (December 1994)(page 12, lines 15-20).

The method of Claim 1 does not appear to be a contribution over the prior art (Lee, Cancer Epidemiology, Biomarkers and Prevention, Vol. 6, pages 443-450, June 1997). Lee teaches CG island methylation changes near the GSTP1 gene in prostatic carcinoma cells detected using PCR. As seen on pages 443, col 2, DNA was isolated, the DNA was amplified using PCR primers of set A and PCR products were electrophoresed to determine the presence. The amplifying step targeted a region within the GST-PI gene and its regulatory

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flanking sequences (Figure 1). Thus, the method does not appear to be a contribution over the prior art. Similarly, Jhaveri (Gene, Vol. 210, pages 1-7, 1998) appears to teach a method which involves amplification of CpG islands within the CSTP1 gene.

The method claims do not require the specific probes and primers of Claims 49-50. The probes and primers are broadly claimed to encompass the full length gene. Therefore, the probes and primers are not a contribution over the prior art.

- 3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg February 19, 2002

Supervisory Patent Examiner Technology Center 1600